



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,910	08/28/2003	Roger P. Jackson	10,126	8690

7590 12/01/2006

John C. McMahon
PO Box 30069
Kansas City, MO 64112

EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
----------	--------------

3733

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,910

Applicant(s)

JACKSON, ROGER P.

Examiner

Mary Hoffman

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-9, 13-14, 16, 18, 22-23, 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Nichols (U.S. Patent No. 6,090,111).

Nichols discloses a polyaxial head bone screw assembly comprising a shank having a threaded body (ref. #24) adapted be implanted a bone, a capture end (ref. #20), and a head (ref. #16) having a channel adapted to receive a rod within the channel, the head having a bore formed therethrough. The capture end of the shank is operably received within the bore of the head. A retainer ring (ref. #42) is secured on the capture end of the shank within the head capable of retaining the capture end within the head and enabling selective angular positioning of the shank with respect the head, while in an adjustment configuration. A closure member (ref. #18) is operably received in the head in such a manner as to be adapted engage a rod located within the channel and to urge the rod into engagement with the capture end of the shank in such a manner so as to fixedly position the head relative to such a rod and to secure the head from angular movement relative to the shank, when in locking configuration. The retainer ring has an outer surface, of which at least a portion is substantially spherical

Art Unit: 3733

(the circumference of ring being the portion that is "substantially spherical"). The head has a seating surface, of which at least a portion is substantially spherical (circumference of annular groove, ref. #54) and the seating surface is capable of enabling slidable mating engagement with the retainer outer surface, when the adjustment configuration, and that frictionally resists relative movement, when in the locking configuration. The capture end the shank has a frusto-conical surface diminishing in diameter toward the shank. (see grooved surface). The retainer ring (ref. #42) has a separation capable of enabling resilient expansion and contraction of the retainer ring. The retainer ring has a substantially radial split capable of enabling resilient expansion and contraction of a diameter of the retainer ring. The capture end of the shank has a non-slip formation (ref. #26) capable of enabling non-slip engagement with a rod. The capture end of the shank has a knurled dome (ref. #26), having a radius, capable of enabling non-slip engagement with a rod within the channel of the head. The cavity has an expansion chamber above the head spherical surface that allows expansion the ring therein as the shank is inserted into the ring.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-14, 16, 18-23, 25-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al. (U.S. Patent No. 6,280,442).

Barker et al. disclose a polyaxial head bone screw assembly comprising a shank having a threaded body (ref. #52/56) adapted be implanted a bone and a capture end

Art Unit: 3733

(ref. #54); a head having a channel (FIG. 3C) adapted to receive a rod within the channel, the head having a bore formed therethrough (FIG. 3C and 3D). The capture end of the shank is operably received within the bore of the head. A retainer ring (ref. #90) is secured on the capture end of the shank within the head capable of retaining the capture end within the head and enabling selective angular positioning of the shank with respect to the head, while in an adjustment configuration. A closure member (ref. #120) is operably received in the head in such a manner as to be adapted engage a rod located within the channel and to urge the rod into engagement with the capture end of the shank in such a manner so as to fixedly position the head relative to such a rod and to secure the head from angular movement relative to the shank, when in locking configuration. The retainer ring has an outer surface, of which at least a portion is substantially spherical (see the circumference). The head has a seating surface, of which at least a portion is substantially spherical (see the circumference of annular groove) and that capable of enabling slidable mating engagement with the retainer outer surface, when the adjustment configuration, and that frictionally resists relative movement, when in the locking configuration. The retainer ring has a frusto-conical retainer bore (see FIG. 6B) formed therethrough capable of enabling mating engagement with the capture end within the retainer bore. The ring has a separation capable of enabling resilient expansion and contraction of the retainer ring (see FIG. 6A). The retainer ring has a substantially radial split capable of enabling resilient expansion and contraction of a diameter of the retainer ring. The capture end of the shank has a non-slip formation capable of enabling non-slip engagement with a rod (ref.

Art Unit: 3733

#58). The capture end of the shank has a knurled dome capable of enabling non-slip engagement with a rod within the channel of the head (ref. #58). The capture end of the shank has a tool formation to enable non-slip engagement by a tool (ref. #60). The head has an internal guide and advancement structure formed therein (see internal threading); and the closure member has a radially outward surface with an external guide and advancement structure (see threading on closure member, ref. #120) formed thereon which is sized and shaped to rotatably mate with the internal guide and advancement structure of the head. The head has an internal thread (ref. #44) formed therein; and the closure member has a radially outward surface with an external thread formed thereon which is configured to rotatably mate with the internal thread of the head.

Claims 1-5, 10-13, 15, 19-22, 24 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrison et al. (U.S. Patent No. 5,891,145).

Morrison et al. disclose a polyaxial head bone screw assembly (see FIG. 2 and FIG.11) for surgical implantation and comprising a shank having a threaded body adapted to be implanted in a bone and a capture end; a head having a channel adapted to receive a rod within the channel, the head having a bore formed therethrough sized and shaped to allow uploading of the shank therethrough and so as to receive the shank when assembled; the capture end of the shank being operably received within the receiving bore of the head; a retainer ring (ref. #50) non integral with the shank and secured on the capture end of the shank so as to rotate with shank relative to the head while in an adjustment configuration and being located within the head to provide a

Art Unit: 3733

shank and retainer ring structure to retain the capture end within the head and enabling selective angular positioning of the shank with respect to the head, while in the adjustment configuration; the shank and retainer ring structure extending into the channel such that upon assembly the shank and retainer ring structure is sized and shaped to be adapted to directly engage the rod; and a closure member operably received in the head in such a manner as to be adapted to engage a rod located within the channel and to urge the rod into engagement with the capture end of the shank in such a manner so as to fixedly position the head relative to such a rod and to secure the head from angular movement relative to the shank, when in a locking configuration. The retainer ring has an outer surface of which at least a portion is substantially spherical. The head has a seating surface, of which at least a portion is substantially spherical and that is sized and positioned to enable slidable mating engagement with the retainer outer surface, when in the adjustment configuration, and that frictionally resists relative movement, when in the locking configuration. The capture end of the shank has a frusto-conical surface (ref. #62) diminishing in diameter toward the shank. The retainer ring has a frusto-conical retainer bore formed therethrough to enable mating engagement with the capture end within the retainer bore expansion of the ring with the ring returning to an original diameter after placement on the shank. The capture end of the shank has a tool formation to enable non-slip engagement by a tool. The head has an internal guide and advancement structure formed therein; and the closure member has a radially outward surface with an external guide and advancement structure formed thereon which is sized and shaped to rotatably mate with the internal guide and

Art Unit: 3733

advancement structure of the head. The head has an internal thread formed therein; and the closure member has a radially outward surface with an external thread formed thereon which is configured to rotatably mate with the internal thread of the head.

Claims 1-3, 5-7, 10-14, 16-17, 19-23, 25-26 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Tatar (U.S. Patent No. 6,113,601).

Tatar discloses a polyaxial head bone screw assembly (see FIGS. 6 and 7) for surgical implantation and comprising a shank having a threaded body adapted to be implanted in a bone and a capture end; a head having a channel adapted to receive a rod within the channel, the head having a bore formed therethrough sized and shaped to allow uploading of the shank therethrough and so as to receive the shank when assembled; the capture end of the shank being operably received within the receiving bore of the head; a retainer ring non integral (FIGS. 3a/b and 4) with the shank and secured on the capture end of the shank so as to rotate with shank relative to the head while in an adjustment configuration and being located within the head to provide a shank and retainer ring structure to retain the capture end within the head and enabling selective angular positioning of the shank with respect to the head, while in the adjustment configuration; the shank and retainer ring structure extending into the channel such that upon assembly the shank and retainer ring structure is sized and shaped to be adapted to directly engage the rod; and a closure member operably received in the head in such a manner as to be adapted to engage a rod located within the channel and to urge the rod into engagement with the capture end of the shank in such a manner so as to fixedly position the head relative to such a rod and to secure the

Art Unit: 3733

head from angular movement relative to the shank, when in a locking configuration. The retainer ring has an outer surface of which at least a portion is substantially spherical. The head has a seating surface, of which at least a portion is substantially spherical and that is sized and positioned to enable slidable mating engagement with the retainer outer surface, when in the adjustment configuration, and that frictionally resists relative movement, when in the locking configuration. The retainer ring has a frusto-conical retainer bore formed therethrough to enable mating engagement with the capture end within the retainer bore. The retainer ring has a separation to enable resilient expansion and contraction of a diameter of the retainer ring. The retainer ring has a substantially radial split to enable resilient expansion and contraction of a diameter of the retainer ring. The capture end of the shank has a tool formation to enable non-slip engagement by a tool. The head has an internal guide and advancement structure formed therein; and the closure member has a radially outward surface with an external guide and advancement structure formed thereon which is sized and shaped to rotatably mate with the internal guide and advancement structure of the head. The head has an internal thread formed therein; and the closure member has a radially outward surface with an external thread formed thereon which is configured to rotatably mate with the internal thread of the head. The cavity has a first region having a partial hemispherical surface sized and shaped to mate with a partial hemispherical surface on the retainer ring; and the cavity has a second region directly accessible from the first region and having a larger radius than the first region wherein the ring is expandable as it joins with the shank.

Art Unit: 3733

With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the above cited prior art, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 3733

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 13, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,716,214. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same invention and contain the same structural limitations, i.e., a screw/threaded shank, head, retaining ring, and closure member.

Claims 1, 13, and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 10/651003. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same invention and contain the same structural limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 13, and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/980534. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same invention and contain the same structural limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 9/06/2006 have been fully considered but they are not persuasive.

Applicant believes that the Nichols (U.S. Patent No. 6,090,111) cannot be used as prior art because it is not "uploaded" the examiner respectfully disagrees, since the term "uploading" is being considered a relative term, and thus, the Nichols reference is being considered being capable of being uploaded, since Applicant has not specified in which direction determines whether or not the shank is being "uploaded". Furthermore, both the rings of Nichols and Barker et al. (U.S. Patent No. 6,280,442) are capable of at least some degree of rotation with the shank, although the direction/angle of rotation may not be the same. For example, both rings are capable of spinning, or rotating, while they are connected to the shank.

Applicant's other arguments are moot in view of the new rejections.

The final rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3733

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

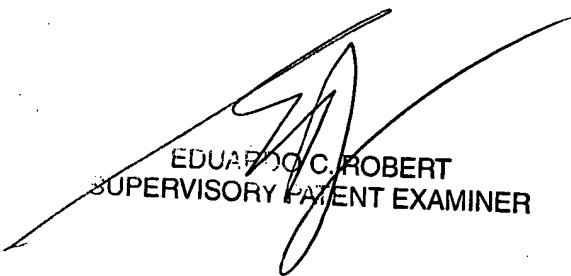
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER